Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the combined effect of nutritional education based on low-calorie foods and physical activity program on treatment of obesity and overweight among primary and secondary school students: A Randomized Trial

Protocol summary

Study aim
Investigating the combined effect of nutritional education based on low-calorie foods and physical activity program on treatment of obesity and overweight among primary and secondary school students

Design
Randomized control trial with parallel groups

Settings and conduct
This study will be conducted among all elementary and high school students in Kermanshah. The calculated sample size will be 524 people who will be divided between two intervention and control groups using random method (Block Randomization). This study will be conducted as a randomized controlled clinical trial for 8 months, and the combined effect of nutritional education and physical activity on the treatment of obesity and overweight students will be measured. Anthropometric and physical activity will be evaluated at the beginning and end of the study.

Participants/Inclusion and exclusion criteria
Obese or overweight students in elementary and high school

Intervention groups
The intervention includes three components, i.e., nutrition education (students and parents), increased physical activity, and changing environment (food items offered in schools' canteens). Nutritionists will provide education to students, parents, and school teachers about healthy eating patterns with emphasis on the consumption of alternative and low-calorie foods, the Iranian food pyramid, and the consumption amount of each food group. Nutrition education will be imparted (a 30-minute session per week) by health instructors; physical activity will be done under the supervision of the school coaches (2 one-hour sessions per week). Parents' education (a 1.5-hour session) will be monthly.

Main outcome variables
Body mass index

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180712040438N6**
Registration date: **2022-11-28, 1401/09/07**
Registration timing: **prospective**

Last update: **2022-11-28, 1401/09/07**
Update count: **0**

Registration date
2022-11-28, 1401/09/07

Registrant information

Name
Jalal Moludi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 41 3335 2148

Email address
jmoludi@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-11, 1401/09/20

Expected recruitment end date
2023-05-20, 1402/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the combined effect of nutritional education based on low-calorie foods and physical activity program on treatment of obesity and overweight among primary and secondary school students: A Randomized Trial

Public title

Investigating the effect of nutritional and physical activity education on obesity

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Desire to cooperate Elementary and high school students Overweight or obese students with a high body mass index (body mass index equal to or higher than the 85th percentile)

Exclusion criteria:

Have a known neurological disease Having major systemic diseases such as malignancies Have known liver disease Taking medications that affect appetite and body weight, such as corticosteroids or other supplements Any possible injury related to the intervention during the study (such as physical harm during physical activity or following the provided diet)

Age

From **7 years** old to **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **524**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method in this study is block randomization. Each of the randomly created sequences is recorded on a card and the cards are placed in the envelopes in order.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kermanshah University of Medical Sciences

Street address

Kermanshah Province, Kermanshah City, Isar Square, next to Farabi Hospital, Faculty of Nutrition Sciences and Food Industry

City

Kermanshah

Province

Kermanshah

Postal code

6719851552

Approval date

2022-10-11, 1401/07/19

Ethics committee reference number

IR.KUMS.REC.1401.301

Health conditions studied

1

Description of health condition studied

Obesity or overweight

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Body mass index

Timepoint

The beginning of the study (before the start of the study), the 16th week and the end of the 32nd week

Method of measurement

Dividing weight (in kilograms) by the square of height (in meters)

Secondary outcomes

1

Description

Energy intake

Timepoint

The beginning of the study (before the start of the study), the 16th week and the end of the 32nd week

Method of measurement

Three-day food recording

2

Description

Waist circumference

Timepoint
The beginning of the study (before the start of the study), the 16th week and the end of the 32nd week
Method of measurement
Tape measure

3

Description
Hip circumference
Timepoint
The beginning of the study (before the start of the study), the 16th week and the end of the 32nd week
Method of measurement
Tape measure

4

Description
The thickness of the skin fold in the triceps region
Timepoint
The beginning of the study (before the start of the study), the 16th week and the end of the 32nd week
Method of measurement
Caliper

5

Description
Physical activity
Timepoint
The beginning of the study (before the start of the study), the 16th week and the end of the 32nd week
Method of measurement
International physical activity questionnaire

6

Description
Stress, anxiety and depression
Timepoint
The beginning of the study (before the start of the study), the 16th week and the end of the 32nd week
Method of measurement
Depression anxiety stress scales

7

Description
Sleep quality
Timepoint
The beginning of the study (before the start of the study), the 16th week and the end of the 32nd week
Method of measurement
Pittsburgh Sleep Quality Index

Intervention groups

1

Description
Intervention group: In the intervention group, nutrition education will be provided to overweight and obese children for 1 hour every week during the 8 months of intervention. These trainings will be with an emphasis on the consumption of alternative and low-calorie foods and the use of a healthy food plate. Students will be advised to do sports activities 3 times a week for one hour each time under the supervision of a sports coach. Educational pamphlets in the field of nutrition and following the food pyramid, as well as sports exercises, are provided to students and their parents at the beginning of the study.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Elementary and high schools
Full name of responsible person
Jalal Moludi
Street address
Kermanshah Province, Kermanshah City, Isar Square, next to Farabi Hospital, Faculty of Nutrition Sciences and Food Industry
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Cyrus Jalili
Street address
Kermanshah Province, Kermanshah City, Isar Square, next to Farabi Hospital, Faculty of Nutrition Sciences and Food Industry
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6719851552
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Email
jmoludi@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor

organization/entity?
Yes
Title of funding source
Kermanshah University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Jalal Moludi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
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Person responsible for scientific inquiries

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Jalal Moludi
Position
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Other areas of specialty/work
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Person responsible for updating data

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Position
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Data collected for the primary outcomes will be shared

When the data will become available and for how long

Accessibility to data is possible 8 months after publication.

To whom data/document is available

The data will only be available for people working in academic institutions.

Under which criteria data/document could be used

The data of the present study will only be accessible by other researchers, for conducting Meta analysis

From where data/document is obtainable

Dr Jalal Moludi, Faculty of Nutrition Sciences and Food Technology, Kermanshah University of Medical Sciences, +989399516766, j.moloudi@yahoo.com

What processes are involved for a request to access data/document

Any one who request our data should provide a brief explanation of the purpose and method of their meta-analysis study. The applicant's request will be reviewed by the researchers and if all agree, the requested data will be sent to the applicant via email in the form of an Excel file. All these steps will not take more than 10 days.

Comments